OGB "PolyCare 2"
Incubator
INSTRUCTION MANUAL

THIS MANUAL HAS BEEN REALIZED
RESPECTING THE ENFORCED NORMS

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1 PRESENTATION

Dear customer,

we would like to thank you for choosing our Incubator "OGB Polycare 2". Ginevri's quality, long experience, safety and easy maintenance will prove to be the best reward for your continuous interest in our products line.

Giorgio Ginevri

GINEVRI s.r.l. – Registered office

Via Giacomo Boni - 00162 Roma

Warning

Before using the device, all personnel, who will be working with the unit, should read and thoroughly understand this manual.

This manual provides instructions for calibration and operator maintenance. Ginevri cannot be responsible for the performance of the Incubator "OGB Polycare 2" if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations in this manual, or effect any repairs with unauthorized components.

Calibration and repair should be performed only by qualified service personnel. Technical information is available through your local distributor.

If there is anything you do not understand, please contact your Ginevri's representative for further information.

GINEVRI srl - Servizio Assistenza Clienti

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This manual refers to the enclosed equipment:

Incubator OGB Polycare 2

S/N _____

2 "EC" CERTIFICATE

CERTIFICATO CE

Certificato n. 747/MDD

Allegato

Incubatrici neonatali da reparto
Modd. OGB Poly Care 1; OGB Poly Care 2; OGB Poly Care 3; OGB Poly Care 4; OGB polytrend.
Marca Ginevri

Incubatrici neonatali da trasporto
Modd. Baby Shuttle Normal Care; Baby Shuttle Special Care; Baby Shuttle Intensive Care.
Marca Ginevri

Isole neonatali
Modd. IW409; IW509; IW909.
Marca Ginevri

Serie: IW509 PLUS.
Marca Ginevri

Serie: Isola Neonatale Modd. ALHENA PLUS ELEVABILE; ALHENA PLUS FISSA; ALHENA ELEVABILE; ALHENA FISSA.
Marca Ginevri

Materassini riscaldanti per uso pediatrico
Mod. Acquatherm.
Marca Ginevri

Analizzatori d'ossigeno
Mod. LCD 1000.
Marca Ginevri

Tende per ossigeno terapia
Modd. Oxytent 1000; Oxytent 2000.
Marca Ginevri

Apparecchi per fototerapia per iperbilirubinemia neonatale
Modd. IP; IPR; RPR; RPS; D; GN; Bililight.
Marca Ginevri

Riscaldatori ausiliari neonatali
Mod. Hot Spot.
Marca Ginevri

Compressori aria per incubatrici da trasporto

Emesso il: 2004-04-21
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IMQ

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3. PRECAUTIONS

3.1-OPERATING PRECAUTIONS

This Instruction Manual must be carefully read and understood by all personnel who install, operate or service the **OGB Poly Care 2** Incubator.
This Incubator should be operated, maintained and repaired in accordance with the instructions contained in this manual.

When use oxygen avoid using alcohol and ether that may cause fire.
Oxygen hoods may increase the noise level inside the incubator.

Slide out the control panel from the base carefully when the heating unit may be still hot.
The heating unit is soundless: internal noise level 45-47dB. Should the noise level increase sensibly, it is advisable to check the unit in order to prevent or limit damages.

Incubator misuse may result in harm to an infant. Incubators should be used only by properly trained personnel as directed by an appropriately qualified attending physician aware of currently know hazards and benefits.

Before using the incubator with patients, the incubator and the accessories should be checked, thoroughly cleaned and disinfected to ensure that equipment is in proper operating condition . See Routine Maintenance instructions.

Direct sun-light or any other external heating sources (like photerapy lamps, radiators) may increase the temperature inside the incubator dangerously. Nevertheless the **OGB Poly Care** separate Max Temperature Audio-visual alarm will activate at 40°C

Remove the control panel from the base carefully when the heating unit may be still hot

The incubator should not be used if it fails to function properly. Service should be referred to qualified personnel.

For safety DO NOT leave the infant unattended when the door is open.

To prevent accidental disconnection, secure all patient leads, infusion lines and ventilator tubing to the mattress with sufficient excess length to allow for the full range mattress height adjustment.

When moving the incubator, two persons of sufficient strength are required for adequate control.

A pre-heating regime of approx. 30 minutes is needed when the incubator is first turned on before use. Therefore, a good and safe standard procedure is to wait until the internal temperature of the incubator has stabilized at the desired level before putting the patient inside.

3.2 ELECTRICAL PRECAUTIONS

To ensure grounding reliability, connect the AC Power Cord only to a properly grounded 3
- wire hospital grade or hospital use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment.

An electric shock hazard exist within the Controller when the cover is removed. Servicing should be performed only by qualified personnel.

Make sure the building power source is compatible with the electrical specifications show on the incubator' s label.

3.3 EXPLOSION PRECAUTIONS

Do not use in the presence of flammable anesthetics.

Make sure that oxygen supply to the incubator is turned off and the incubator is disconnected from the oxygen supply when performing cleaning and maintenance procedure; a fire and explosion hazard exists when performing cleaning and/or maintenance procedure in an oxygen – enriched environment.

Keep matches, lighted cigarettes, and all other sources of ignition cut of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

4. INTRODUCTION

The philosophy that has guided GINEVRI in the design of their products for the last 40 years is ***Maximum Performance***, and ***User Friendliness*** at the same time. This philosophy has conducted to the line of incubators OGB *Poly Care*.

Poly care control units are microprocessor driven and can control all the parameters necessary to obtain the ideal environment for the premature baby. Depending on the model is possible to monitor and control:

- Temperature (Air, Skin) with proportional heating;
- Humidity, with an integrated sterile humidity generating system;
- Oxygen concentration in the hood or in the head-box;

Data are displayed on big, clear colour displays and the desired parameter values are set trough soft-touch sealed keys arranged in an intuitive and error-free pattern.

The intensive care incubators can be equipped with the revolutionary *Hot-Spot* radiant heater, when this system is fitted the baby skin temperature is maintained constant even with both doors open, thus eliminating the clumsiness of the double wall and the danger of the air curtain.

Technology and materials
The choice of materials and technologies employed is what makes the difference in the new generation of incubators. Hood, base and main components of the *Poly Care* incubators are injection-moulded in Polycarbonate (Lexan).
Poly Care incubators are «unique» for their design, features and manufacturing technologies, on the market it is impossible to find apparatus with all this features at the same time.
The injection-moulding in a single block , the absence of glued junctions and the round shapes improve the air circulation, reduce the internal noise level and allow a radical cleaning and sterilisation. All this features and details guarantee the incubator optimal performance.

To order a spare part from every part of the world what you need is just a fax and a part number.
The technical solutions employed for the *Poly Care* incubators make maintenance and servicing easy and economical. Even the need for specialised service engineers is no longer required. This happens because the mechanical components, manufactured with a moulding process, are all strictly identical and because, thanks to digital electronics, servicing means only changing a board or a probe.

Incubator base, control panel, humidifier, patient tray and *Smooth-Tilt*, are all injection moulded in Polycarbonate (Lexan).
Polycarbonate is unbreakable, high temperature resistant, fire retardant, disinfectants and chemicals resistant. Thanks to the materials and the technologies employed the apparatus can be completely disassembled without tools in a few minutes.

The hood of *Poly Care* incubators is made in lexan too, this material is, unbreakable, heat resistant (up to 150°C), durable. The single piece injection moulding and, therefore, the absence of joined or glued parts, guarantees hygiene and sterility.

For all this reasons Lexan hoods outperform under every aspect traditional acrylic plexiglas hoods.
For an optimal access to the patient the doors on the two sides of the hood can be completely

opened and when open, the hood top is still accessible. The hood is equipped with six port-holes provided of dampened opening.

5. GENERAL INSTRUCTIONS

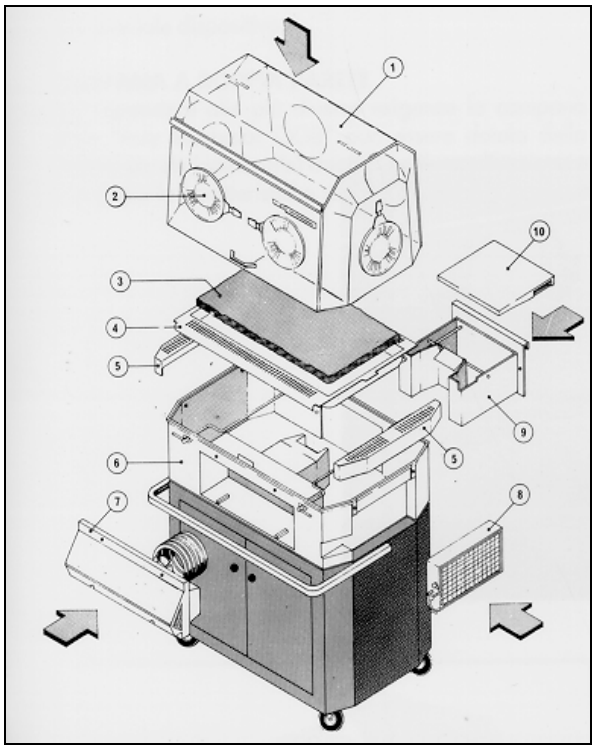
5.1 GENERAL DESCRIPTIONS

The ***OGB POLY CARE 2*** is a fully microprocessor driven Infant Incubator to provide both air and skin temperature control.
In addition, the heater output is proportional to the heat required by the little patients to maintain their own temperature and it is shown by the led bar scale changes. Heat outputs vary according to babies' needs and their dependence upon incubator, in order to create the best environmental conditions for the little patients, minimise temperature fluctuations and gradually wean the babies from the incubator system.

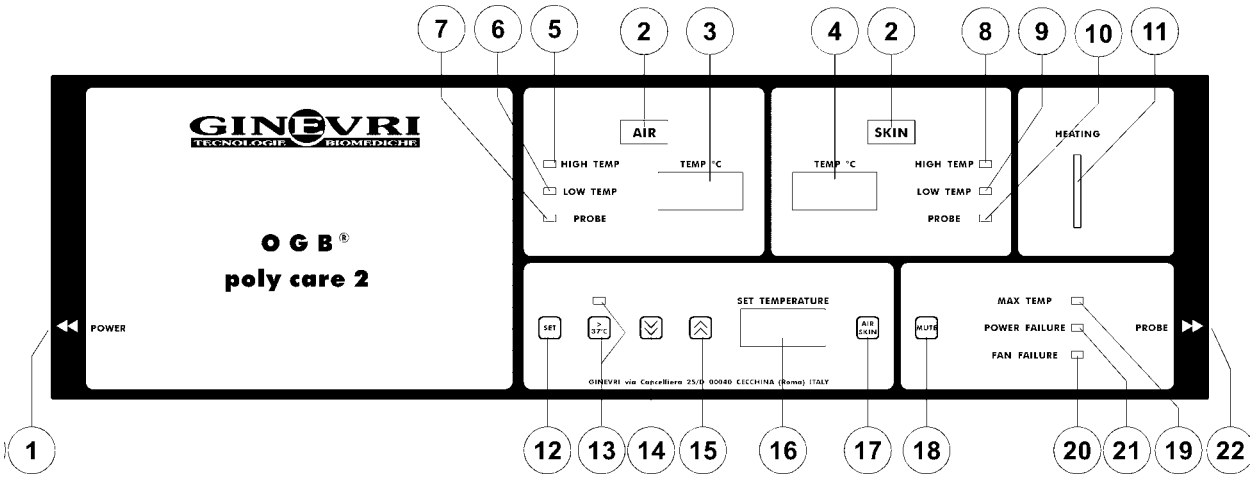
The ***OGB POLY CARE 2*** system provides:
a) accurate and automatic air temperature adjustment to achieve patient's set temperature;
b) temperature constant monitoring with high/low temperature alarms;
c) uniform temperature values inside the hood;
d) an indication of when it suitable to suspend the treatment, being the set patient temperature achieved without heat outputs (the led bar showing proportional heating is off).

OGB POLY CARE 2 Assembly mounted on closed cabinet trolley:

1. One piece injection moulded polycarbonate transparent hood;
2. Port holes with sleeves and door releases;
3. Fire retarding mattress;
4. Polycarbonate patient tray equipped with *Smooth-Tilt* for the smooth adjustment of the posture bed in the Trendelemburg and Fowler positions;
5. Polycarbonate baffles;
6. Polycarbonate base complete with a humidity system and a air microfilter;
7. Removable Control Panel (housed in the incubator base);
8. Air and /or O2 microfilter (filtering capacity 0,5 micron)
9. Polycarbonate removable humidifier. It refills externally.
10. Humidifier cover lid equipped with device for the adjustment of RH inside the hood.



The ***OGB POLY CARE 2*** power requirements are 220V - 50/60 Hz.



5.2 CNTROL PANEL

1 **ON/OFF (1) Green Switch** : the unit turns on/off when the switch is pressed/depressed. The power failure alarm operates if the switch is ON and the Power cord is unplugged or there is not Power Supply.

2 **AIR or SKIN (2) Mode Led Indicator**, lights when Air or Skin is selected.

3 **Actual Air Temperature (3)** in the hood in °C.

4 **Actual Skin Temperature (4)** measured by the skin probe in °C.

5 **High Air Temperature Alarm (5)**, it activates when the temperature inside the hood is 1°C higher than the set point. It blinks if muted.

6 **Low Air Temperature Alarm (6)**, it activates when the temperature inside the hood is 3°C lower than the set point. It blinks if muted.

7 **Air Temperature Probe Failure Alarm (7)**.

8 **High Skin Temperature Alarm (8)**, it activates when the baby temperature is 1°C higher than set value. It blinks if muted.

9 **Low Skin Temperature Alarm (9)**, it activates when the baby temperature is 1°C lower than the set value. It blinks if muted.

10 **Skin Temperature Probe failure Alarm (10)**.

11 **Led Bar (11)**, showing the heat output percentage.

12 **SET Key (12)**, press and hold to set either Air and Skin temperature using the temperature arrows keys **(14)** to lower and **(15)** to raise**.**

13 **>37 Key (13),** press and hold to set either Air or Skin temperatures above 37°C using the temperature arrow key **(15).**

14 **Temperature «Down» Arrow key (14),** (it operates keeping Set Key **(12)** pressed).

15 **Temperature «Up» Arrow key (15),** (it operates keeping Set Key **(12)** pressed).

16 **Skin Set Temperature Display (16).** It shows either Set Air or Skin Temperature according to the selected mode.

17 **AIR-SKIN Key (17)**, press to select between AIR/SKIN mode (it operates keeping Set Key **(12)** pressed).

18 **MUTE Key (18)**, it mutes the audible alarms.

19 **MAX Temperature Alarm (19)**, it activates at 38°C when the set temperature is $\leq$ 37°C or at 39°C when the set temperature is > 37°C. A separate Max Temperature Alarm will activate automatically at 40°C for any Set Temperature or over heating due to external sources (sun-ray, phototherapy lamps, radiators) and shut off the heating.
This alarm cannot be muted

20 **Fan Failure Alarm (20)**, in case of fan malfunction it activates and the heating is shut off.
This alarm cannot be muted

21 **Power Supply Failure Alarm (21)**.
This alarm cannot be muted

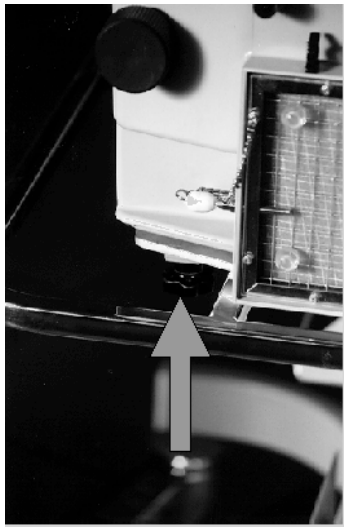
22 **Separate Sockets for Skin and Air probes (22)**.

5.3 UNPACKING

Typically, OGB Poly Care Line Incubators are shipped completely assembled in a wooden crate. Pay attention not to scratch or damage the surfaces removing the packaging materials.

5.4 INCUBATORS ASSEMBLY

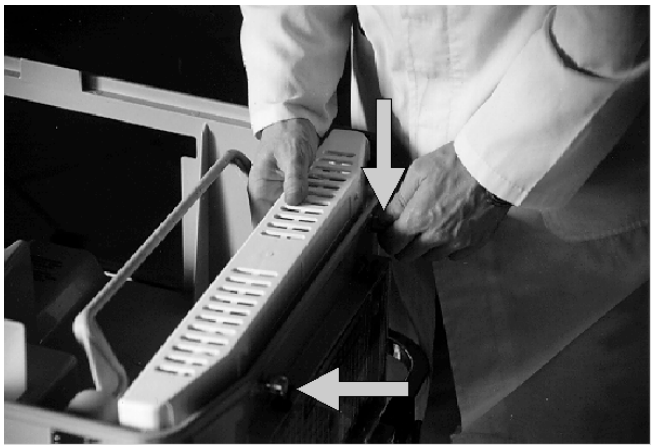
OGB Poly Care line Incubators are designed to allow an easy maintenance, disassembling and sterilisation.
Electrically powered elements are included in the control panel which can be easily with removed simply loosening four thumb screws.
All the components can be disassembled without using tools.



5.4.1 Base

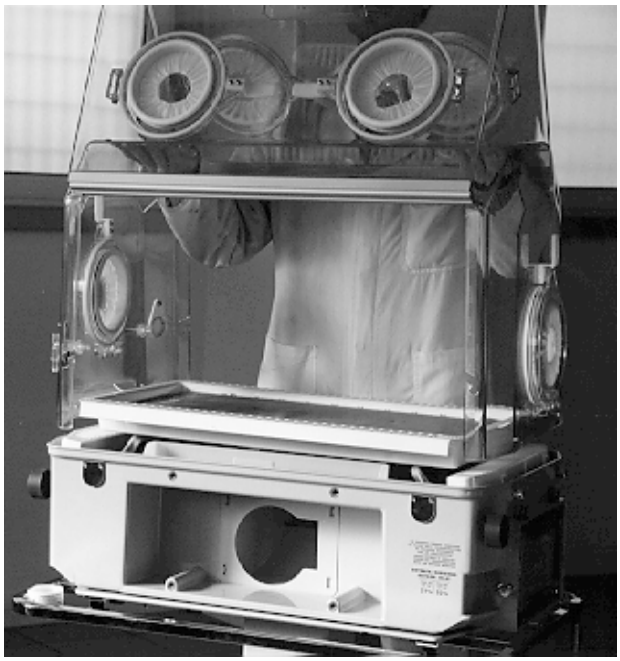
To avoid the Incubator tilting or falling, secure the Base to the cabinet as shown.
Place the Base on the stand and secure it using the clamping knobs on each edge.
Check to be certain Incubator is firmly secured to the stand . Do not place in service if not.

Install the Deflector on the base as shown .



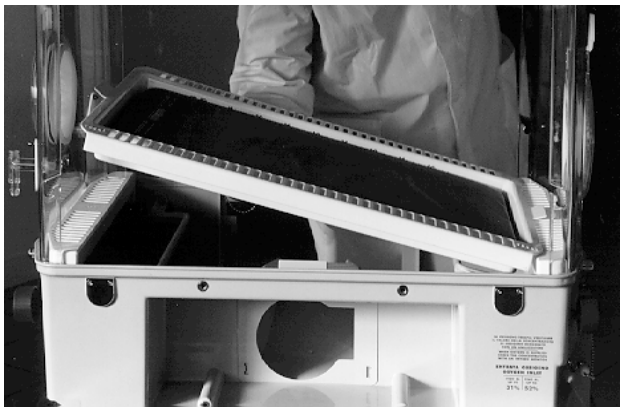
Secure both the Lexan baffles with the threaded pins supplied.

5.4.2 Hood



Lift the Hood as shown and place it on the base properly aligned on the threaded pins of the baffles. Secure the pins fast.

Lower both the elevators of the Tray Tilt Mechanism ***Smooth-Tilt*** turning the blue knobs on the left and right side of the base. Install the mattress tray as shown.



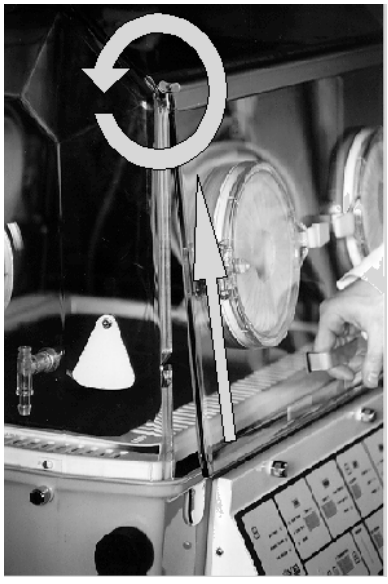
Both the doors are connected to the hood by means of a «slide out» type hinge in one piece with only two mounting screws for an absolute sterilisation as there are no hidden areas or critical points.

To disassemble the doors loose both the screws and slide the hinge out.

Both the doors should be kept close during routine operation. For infant safety, do not leave the infant unattended while the doors are open.

WARNING

Closing the doors, check that the bottom side of the door is inserted in the base slot as shown in the figure.



5.4.3. Micro-Filter

Install an Air Filter, with a filtering capacity not lower than 0.5 µm, on the right side of the unit as shown.
Do not attempt to clean, wash or sterilise the micro-filter to use it again. The micro-filter should be replaced (P/N 409 for an order) for every new patient and checked on routine basis. Before installing a new filter, clean the Microfilter chamber.

WARNING

A dirty micro-filter may:

- contaminate the air circulating in the hood
- obstruct the air intake
- affect oxygen concentration
- cause carbon dioxide built-up

Before installing a new filter, clean the micro-filter chamber.
Instructions to replace the filter:

- remove air intake filter cover by pulling it out by means of the handle placed on the right side of the cover (as shown in the figure).
- Clean the micro-filter chamber and cover. Before installing the new filter, take note of the date replacing and write it down in the appropriate space on the right side of the filter. Install the new filter. The date must be always visible.

N.B. Ginevri s.r.l. cannot be responsible for the malfunctioning of the equipment and injury of the operator and/or patient which may be caused by the use of other types of filters.

5.4.4. Control Panel

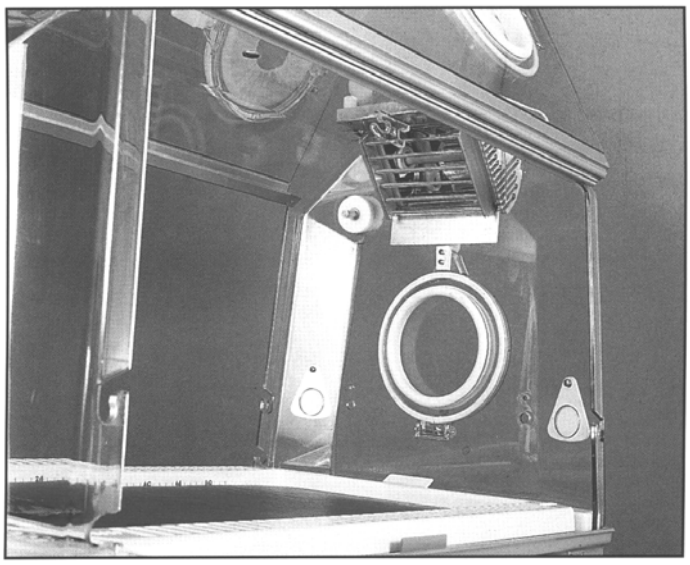
Install the Control Panel and secure it with the supplied thumb screws.

WARNING

The Controller heater can be sufficiently hot to cause burns; avoid moving or touching it until the unit has been switched off for at least 30 minutes.

5.4.5 Radiant Heater Hot Spot

OGB ***Poly Care 2*** can be equipped with new ***Hot Spot*** system (optional).
The ***Hot Spot*** is an infrared radiant heater controlled by the incubator SKIN Mode operation system which allows to maintain constant pre-set baby skin-temperature even with both incubator doors open.



The system consists of:

1 Hood port cover lid

2 Radiant heater

3 ***Hot Spot*** module

- Remove the port cover lid from the hood right side.
- Insert the Radiant Heater through the port on the hood right side and secure it using the two thumb-screws supplied for the port cover lid.
  WARNING
  Check that both thumb screws are fully tightened before proceeding.
- Insert the ***Hot Spot*** module into the slot on the right side of the trolley.
- Secure the cable connecting the radiant heater and the module with the clamps provided.
- Loosen the screw-cap of the Hot Spot cable socket on the right side of the control panel. This socket is labelled: ***Hot Spot***
- Screw ***Hot Spot*** module cable to the socket.
- Press the switch on the Hot Spot Module to power the system on.

Hot Spot will now automatically adjust radiant heater output to correct the difference between the actual patient temperature and the required level set by the user.

CAUTION
Hot Spot activates only when OGB ***Poly Care 2*** is operating in SKIN Mode Control. A pulsating audible alarm indicates that the system is on. This alarm is self-resetting and reactivates automatically after a 10 minute delay.

WARNING

HOT SPOT SHOULD BE USED WITH A LEAST ONE DOOR OPEN. IF BOTH DOORS ARE CLOSED DO NOT ADMINISTER OXYGEN.

6 - OPERATION

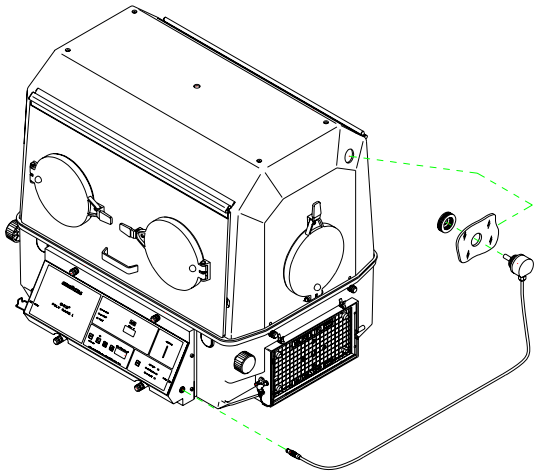
6.1 OPERATING INSTRUCTIONS

1. Connect the power cord to 220V-50Hz.

2. Press ON the Power supply Switch **(1).** The display panel will show the memorised values.

3. Connect the plug of the Air Probe to the Air Probe socket (22).

4. Insert the probe end through the hole on the top of the hood as shown in the Figures. Air Temperature value will be displayed on (3).



5. Connect the plug of Skin Probe to the Skin Probe socket **(22).** Insert the probe into the hood through one of the access for tubing.

6. When the infant is on its back or side, put the tip of the probe to the midline of the abdomen, halfway between the umbilicus and the xyphoid**.** When the infant is prone, the probe should be on the infant's back. The skin area where the probe is to be placed should be thoroughly cleaned and dried before the probe is placed on the skin. The Skin Probe must be attached in complete contact with the skin. Ginevri heart shared ***Reflectors*** (p/n 565) are designed for this purpose.

WARNING

The probe must never be placed under the infant or used rectally.

7. Skin Temperature value will be displayed on **(4).**

8. Check the water level of the humidifier reservoir, and if necessary fill it to the gauge line with sterile distilled water.

9. When the oxygen therapy is necessary, insert oxygen plugs into the oxygen inlet on the right side of the incubator and use an Oxygen Analyser (**LCD 1000** Monitor manufactured by GINEVRI) in order to check the oxygen concentration.

10. Preheat the incubator until the temperature inside the hood is stabilised at the set value.

11. If the temperature external is higher than that required by the patient, put some ice inside the humidifier reservoir. In this way, the temperature decreases and the operator may set the right value.

12. The ***OGB Poly CARE 2*** is provided with a set of 4 probes that guarantee the utmost reliability. Two probes monitor the Air temperature. The second Air probe becomes operative whenever the first probe fails. In this case the probe alarm **(7)** is flashing. Should be both the probes faulty, the probe visual alarm light is steady. The third probe (Skin probe) monitors the Skin temperature, in case of failure, the probe audio-visual alarm **(10)** activates and the incubator will start to operate automatically in Air Mode at 33 °C. The fourth probe is connected to the Max Air Temperature alarm with separate safety circuit.

6.2 OPERATION MODES

The microprocessor system controls both Air (AIR Mode) and Skin (SKIN Mode) temperature with proportional heating. The heating percentage is displayed on a 5 segment LED Bar.

6.2.1 Air Temperature Control

The Air temperature control activates automatically at 33°C when the incubator starts to work. The microprocessor system controls air temperature with proportional heating. The heating percentage is displayed on a 5 segments LED Bar **(11).**
To change Air Temperature from 20°C to 37°C press SET key **(12)** and **(14)** or **(15)** keys at the same time to decrease or increase temperature (0,1°C step).
To increase temperature over 37°C press **(12)** key and **(13)** key at the same time.
The pre-set temperature values are memorised and they will be stored in case of power failure or black out.

Actual air temperature is displayed by the Air temperature display **(3).**

High/Low Air Temperature Alarms

The high and low temperature alarms **(5)** - **(6)** are automatically pre-set setting a new temperature. The alarm activates when actual air temperature is 1°C higher than set temperature or 3°C lower than the set temperature.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will reactivated.

Max Air Temperature Alarm

If the set temperature is lower or up to 37°C, an audio-visual Max Temperature alarm **(19)** activates when the temperature exceeds 38°C. If the set temperature is between 37°C or 38°C an audio-visual alarm activates **(19)** when the temperature exceeds 39°C. This alarm cannot be muted until the Max Temp. alarm condition is corrected.

6.2.2 Skin Temperature Control

Skin temperature activates automatically at 36 °C when the incubator starts to work. The relative amount of heat being provided to achieve set Skin temperature is displayed on a 5 segments LED Bar **(11).**
Press Set key **(12)** and AIR/SKIN **(17)** key to set SKIN Operation Modes.
To change Skin Temperature from 25°C to 37°C press SET key **(12)** and **(14)** or **(15)** keys to decrease or increase temperature (0,1°C step).
To increase temperature over 37°C press **(13)** and **(15)** key at the same time.
The pre-set temperature values are memorised and they will be stored in case of power failure or black out.

A temperature sensing probe is attached directly to the infant's skin; the information from the probe is supplied to the heater control circuitry which proportions the heater output to maintain the Baby's Temperature at the set Skin Temperature.

Actual baby temperature is displayed by the Skin temperature display **(4).**

High/Low Skin Temperature Alarm

The high and low temperature alarms **(8)** - **(9)** are automatically pre-set when setting a new temperature. The alarm activates when skin temperature is either 1°C higher or lower than the set skin temperature.
If the MUTE key **(18)** is pressed during an alarm condition, the audible alarm is suppressed but the light goes on flashing. If the alarm condition is not corrected within 10 minutes, the audible alarm will reactivated.

6.3 ALARM DEVICES

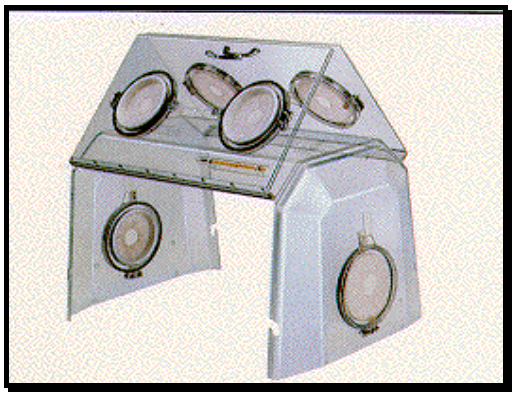
6.3.1 Power Failure Alarm

The power failure audio-visual alarm **(21)** will sound when the power supply is interrupted.
Check the power failure alarm for proper operation before using the incubator. Remove the power cord from the wall outlet, the buzzer should sound.
This alarm cannot be muted until the alarm condition is corrected. In this case is necessary to reset the system setting the incubator Power switch to off before proceeding.

6.3.2 Fan Block Alarm

If the fan assembly is faulty the audio-visual alarm **(20)** activates indicating the fan-block.
This alarm cannot be muted until the alarm condition is corrected. In this case is necessary to reset the system setting the incubator Power switch to off before proceeding.

6.4 HOOD ASSEMBLY



The hood is made of one-piece polycarbonate injection moulded in one piece. Lexan (Polycarbonate) is more performing than traditional Acrylic Plexiglas and it has the following features:

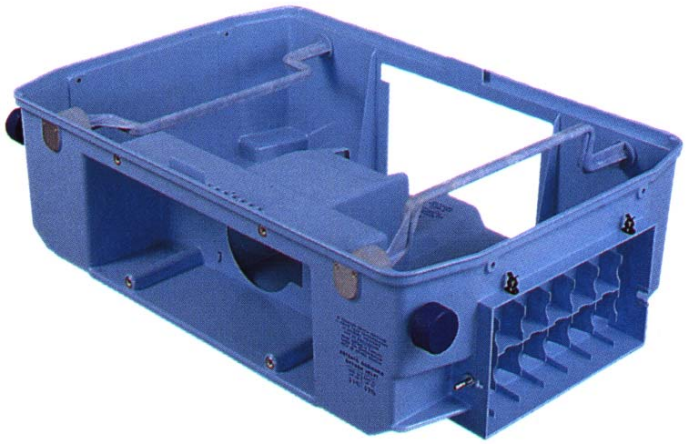
- UNBREAKABLE;
- MOULDED IN A SINGLE PIECE WITHOUT JUNCTIONS, for an easy and absolute sterilisation;
- ATHERMIC: it does not disperse heat and guarantees against contact burns;
- SILENT: it guarantees minimum noise inside the incubator (less than 45 dB);
- FIRE RETARDING;
- HIGH TEMPERATURE RESISTANT (150°C);
- CHEMICALS PROOF;
- NON-TOXIC.

OGB Poly CARE 2 Incubator outperform in every aspect the traditional incubator Acrylic/Plexiglas hoods.
This means also:

- Improved internal visibility;
- Easy cleaning and sterilisation;
- No image distortion;
- Unequalled Width.

The incubator hood is fitted with 6 portholes and two opening doors. The two doors can be swung open up simultaneously and keep the hood roof free.
When closing the doors, be sure they rest inside the front lip. The hinged system allows easy cleaning and maintenance. The six portholes, each one with sleeves, allow access to patient without altering the microclimate.
Slotted tubes openings and holes are provided at the sides of the hood. The baby can be removed from the incubator without disconnecting tubes.

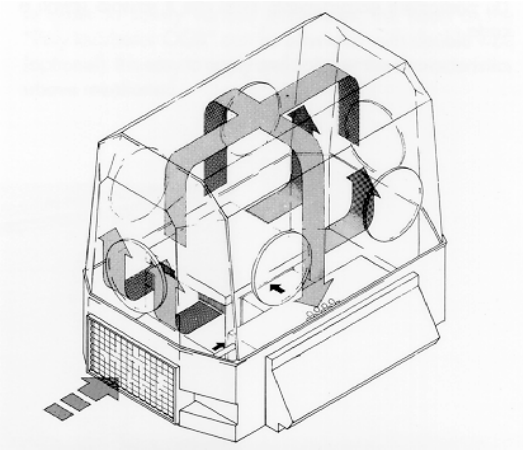
6.5 BASE



The base is made of polycarbonate injection moulded in one-piece, with smooth edges to avoid damages in case of crashes or bump.
The assembly allows easy cleaning and maintenance. The base consists of patient bed tray, microfilter assembly, humidity reservoir, oxygen inlets.

6.6 AIR CIRCULATING SYSTEM

The air circulating system provides a constant interchange of air. An induction fan drives external air into the unit through a microfilter system.
After passing through the filter, the air is sucked into the heating compartment where it is heated. A special deflection system, controlled from the outside, drives the air partially or wholly into the humidity reservoir, depending on the relative setting of the humidity control.



CAUTION
Proper temperature control depends on continuos, unobstructed air circulation.
Do not attempt to decrease temperature by shutting off power since air circulation will stop. Press the temperature keys when increasing or decreasing temperature.
Do not cover air circulation openings around the bed as obstruction will result in loss of air circulation and loss of heat.

6.7 OXYGEN CONCENTRATION CONTROL

The ***OGB Poly CARE 2*** is provided with two inlets for controlled administration of pure oxygen, and both inlets are located on the filter unit.
A **31%** oxygen limiting inlet is on the left hand of the microfilter and a **52%** limiting oxygen inlet is on the right hand of the microfilter.
Oxygen concentration higher than 52% could be dangerous for infants. They can increase the risk of retinopathy. Therefore, arterial blood gas monitoring is extremely important when oxygen enriched environment is necessary.
OXYGEN CONCENTRATION SHOULD BE CHECKED WITH AN OXYGEN ANALYSER AND A PULSE OXYMETER.

6.7.1 Oxygen Concentration Table

with the flowmeter and the oxygen hose connected to the 31,5% inlet

Rate of Flow	**Oxygen Concentration**
l.p.m. 1	22,7 %
l.p.m. 2	23,7 %
l.p.m. 3	25,1 %
l.p.m. 5	29 %
l.p.m. 6	29,7 %
l.p.m. 7	30,3 %
l.p.m. 8	31 %
l.p.m. 9	31,5 %
l.p.m. 10	31,5 %

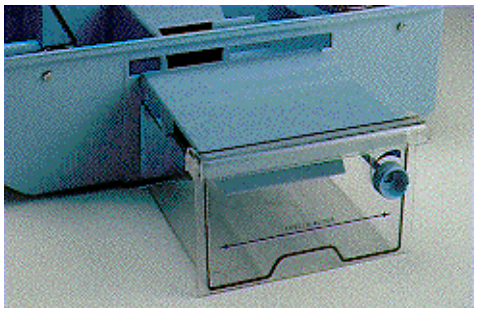
6.7.2 Oxygen Concentration Table

with the flowmeter and the oxygen hose connected to the 52% inlet

Rate of Flow	**Oxygen Concentration**
l.p.m 5	31 %
l.p.m. 10	43,5 %
l.p.m. 15	43,5 %
l.p.m. 18	46 %
l.p.m. 20	51,5 %
l.p.m. 25	52 %
l.p.m. 30	52 %

6.8 HUMIDITY SYSTEM

The humidity system consists of a transparent polycarbonate tank, housed in Incubator Base rear side, allowing water level constant monitoring.
This system allows to adjust the RH level up to 90% turning clockwise the blue knob.
The water tank can be withdrawn from the base simply pressing the latches on the left and right side of the same. This allows the cleaning and sterilisation of the reservoir avoiding condensation and spores depositing.



It is possible to remove the reservoir when the patient is inside the incubator.
Fill the reservoir to the gauge line with sterile distilled water.
When removing the reservoir, it is possible to remove also the humidity control system without using any special tools.
Since tubing, screws have been avoided, the humidifier can be easily disassembled for an absolute cleaning.
Condensation may form on the inside of the hood at the

higher humidity values settings. The amount of condensation will depend on the difference between room temperature and incubator temperature.

The humidity level should range from 50% to 65%. Microclimate hoods are suggested when a humidified, high temperature, oxygenated environment is considered necessary.

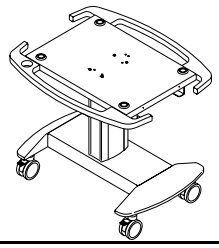
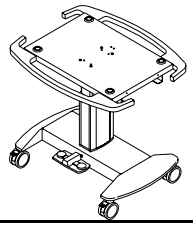
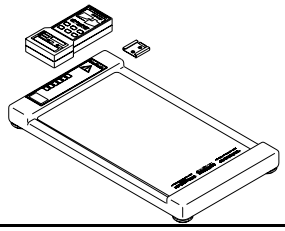
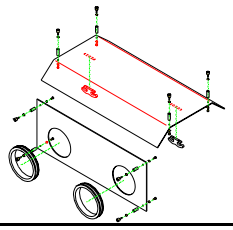
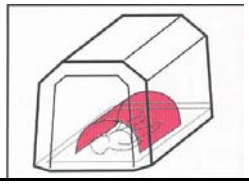
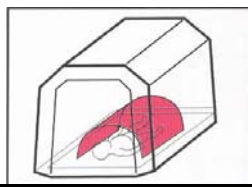
We list below a table of ranges depending on three different knob positions : MINIMUM - MEDIUM - MAXIMUM.

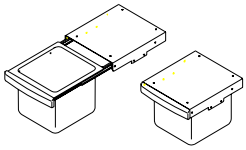
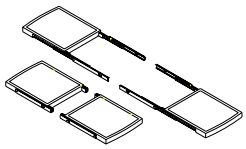
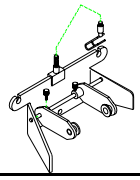
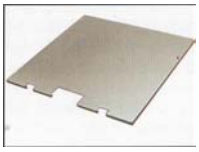
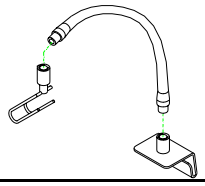
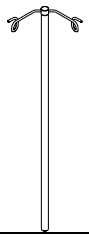
AMBIENT TEMPERATURE	**ROOM HUMIDITY**	**INCUBATOR TEMP.**	**INCUBATOR HUMIDITY Minimum - Medium - Maximum**		
24°C	52%	32°C	60/65	65/75	75/90
		35°C	53/63	63/73	73/83

PATIENT BED TRAY

The baby's bed is polycarbonate made. ***OGB Poly CARE 2*** is equipped with Smooth-Tilt, a new bed positioning system which allows the continuous and smooth adjustment of the posture bed in the Trendelemburg and Fowler positions turning the knobs placed on both the left and the right side.

7 ACCESSORIES

Ref.	P/N-code	Description	Figure
1	11400A70	TROLLEY WITH CENTRAL AXIS FIXED	
2	11410A70	TROLLEY WITH CENTRAL AXIS HEIGHT-ADJUSTABLE	
3	8040	BABY SCALE "BILLA"	
4	12085A70	DOUBLE WALL HOOD WITH OVAL PORT HOLES	
5	7533	HOT SPOT	
6	559	MICROCLIMATIC HEAD BOX 30 X 20 X 13 CM	
7	589	MICROCLIMATIC HEAD BOX 35 X 25 X 15 CM	

8	**1521**	**I.V. POLE COMPLEX**	
9	**6922**	**I.V. POLE STANDARD**	
10	**722**	**POSTURE COT**	
11	**11401A70**	**DRAWER**	
12	**11405A70**	**RETRACTABLE SHELF**	
13	**7647**	**BABY HEAD IMMOBILIZER WITH VENTILATED HOSE HOLDER**	
14	**1693**	**X-RAY FILM PLATE**	
15	**5740**	**PIVOTING SHELF**	
16	**10712A70**	**VENTILATOR HOSE HOLDER**	
17	**634A70**	**AUCTION FLEBO**	

8 - OPTIONALS

8.1 TROLLEYS (optional)

Ginevri's trolleys are designed to enhance manoeuvrability and lightness. They can be equipped with shelves for accessories and module with drawers.
They are mounted on four big-diameter pivoting castors with foot brakes.
A stainless steel safety guard rail is provided.

Different models are available:
- TROLLEY WITH CENTRAL AXIS FIXED (p/n 11400A70)
- TROLLEY WITH CENTRAL AXIS HEIGHT-ADJUSTABLE (p/n 11410A70)

8.2 ***IV POLE*** (optional)

It consists of stainless steel stand for supporting equipment and bottles.

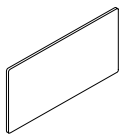
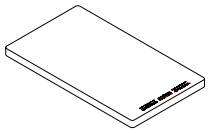
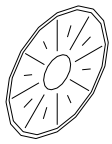
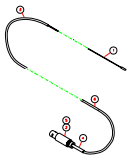
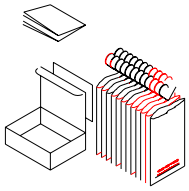
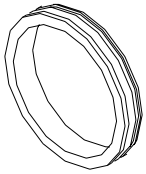
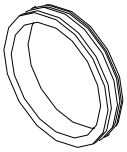
8.3 SCALE (optional)

An Electronic baby scale BILLA is available for weighing the baby in the incubator.
BILLA baby scale consists of a weighing tray, compatible with standard incubator trays, a microprocessor control unit and a AC adapter. BILLA baby scale detects weight changes during the day with e resolution of +/- 1 gr.
Range from 1 gr. To 10.000 gr. With 1 gr. Step.

8.4 X-RAY FILM PLATE (optional)

The X-Ray film plate provides a large flat surface necessary for X-Ray examinations.
Elevate both ends of the Tray Tilt Mechanism Smooth- Tilt turning the blue knobs on the left and right side of the base and place the X- Ray plate under the tray inserting it from the rear side.

9 SPARE PARTS

Rif.	Code	Description/Image		Q.ty
1	11130A72	AIR FILTER		Cf. pz. 12
2	434	MATTRESS		Cad.
3	11725A73	SLEEVE		Cf. pz. 12
4	11461A72	THERMOMETRICAL PROBE		Cad.
5	565	ADHESIVE REFLECTORS "GEL REFLECT"		Cf. pz. 24
6	1711A	REBRIL DETERGENT (Conf. da 2 Kg.)		Cad.
7	11721A73	SLEEVE OVAL GASKET		Cf. pz. 6
8	12029A73	FLANGE FOR ROUND DOOR		Conf. pz. 6

10 ROUTINE MAINTENANCE

10.1. MICROFILTER

The micro-filter should have a filtering capacity not lower than 0.5 μm.
The micro-filter should be replaced for every new patient and checked on routine basis.
Do not attempt to clean, wash or sterilise the micro-filter to use it again.

WARNING

A dirty micro-filter may:

- contaminate the air circulating in the hood
- obstruct the air intake
- affect oxygen concentration
- cause carbon dioxide built-up

Before installing a new filter, clean the micro-filter chamber.

10.2 CLEANING AND STERILISATION

All the components of the ***OGB Poly CARE 2*** can be easily disassembled, without additional tools, for cleaning and maintenance.
GINEVRI cleaning detergent (p/n 1711) may be used for cleaning of any component.
The special alkaline and soluble solution avoids calcareous depositing.
It does not corrode metals and plastic materials.
The special detergent substance is not harmful for the operator.
Don't use abrasive or highly alkaline cleaners.
Never scrape the sheet with squeegees, razor blades or other sharp instruments.
Don't clean the incubator when it is still hot

10.3 DISASSEMBLY

Open front door and lift out the bed tray.
The hood can be removed from the incubator body loosening the retaining screws which hold the bed spacers. Remove the bed spacers from the hood and remove the hood from the body by lifting it up as shown at page 12.
Place the hood on a flat surface.

10.4 DUSTING

Dust the hood with a clean and soft cloth or paper towel.

10.5 WASHING

After removing all solid wastes and contaminants from the disassembled parts, use a disinfectant-detergent and hot water to thoroughly clean all surfaces with a clean soft cloth, sponge or paper towel. Make sure to clean all holes, baffles, access doors, hand doors etc.
The base, the hood, the water tank, the bed tray, the baffles etc. can be autoclaved (Max 100°C) since they are made of polycarbonate.

10.6 DRYING

Dry the washed surfaces using a clean dump cloth.
Do not use a dry or rough cloth not to scratch the surfaces..

10.7 HEATING UNIT

Disconnect the power supply from the heating unit before cleaning.
Remove the heating unit loosening the 4 nuts. The front panel can be cleaned with a damp cloth and cleaning agent.
The heating element can be dipped in a liquid sterilisation agent. Care must be taken to prevent liquids from coming in contact with electrical parts of the unit.

11 - TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	REMEDY
- No power , POWER FAILURE Alarm is not activated.	- POWER switch not on.	- Depress POWER switch .
	- Fuse failure.	- Replace fuse.
- POWER FAILURE alarm activated.	- Power cord unplugged.	- Verify power cord is correctly plugged in.
- MAX TEMP activated.	- External source of heating.	- Eliminate external source of heating
- FAN FAILURE activated.	- Dirty fan failure sensor. - Obstructed air circulation system. - Fan motor failure.	- Clean the sensor with a soft clouth. - Remove obstruction. - Replace fan a/or motor.
- LOW TEMP alarm activated.	- Door(s) left open. - Skin probe not properly secured to skin (Skin Mode operation only).	- Close all doors. - Check Skin Probe positioning.
- SKIN PROBE alarm activated.	- Skin probe plug not proberly connected. - Probes unit plug not properly connected	- Verify skin probe plug connection. - Verify probe plug connection.

12 - TECHNICAL DATA SHEET

INCUBATOR BODY	One piece injection moulded
ELECTRICAL POWER SUPPLY	220V 50/60 HZ
ELECTRICAL CONSUMPTION	330w (540w With Hot Spot)
SAFETY CLASS (IEC 601.1/CEI 62.5)	1st
CATEGORY (IEC 601.1/CEI 62.5)	B
MEDICAL DEVICE CLASS (93/42/CEE)	II B
GROUND LEAKAGE CURRENT	50 µA
PROTECTION	2 Fuses 5x20 mm 2 Amp F (3.15Amp F)
POWER FAILURE ALARM	Included
POWER FAILURE ALARM BATTERY	Included
AIR TEMPERATURE INDICATOR	0.1°C Resolution, 0.6°C Max Error
SKIN TEMPERATURE INDICATOR	0.1°C Resolution, 0.3°C Max Error
AUTOMATIC TEMP. ADJUSTMENT WITH PROPORTIONAL HEATING	20°C to 38°C Air / 25°C to 38°C Skin
MAX TEMPERATURE ALARM	Audio-visual alarm stops heating Automatically at 38°C or 39°C
HUMIDITY CONTROL	50% to 90%
IDEAL ROOM TEMPERATURE	21°C to 26°C
HUMIDITY RANGE OF THE ENVIRONM.	35% to 90%
STORING TEMPERATURE	-10°C TO +50°C
NOISE LEVEL INSIDE THE HOOD	Lower than 45 – 47dB
VENTILATION	36 Lt. Minute multi-direction
MAXIMUM CO2 CONCENTRATION (MEASURED UNDER IEC 6012 – 19 TEST CONDITIONS)	<0.5%
MAX WEIGHT FOR THE BED TRAY	10 Kg.
DIMENSIONS:	
- INCUBATOR …….	83x59x68cm (W,D,H,) approx.
- HEIGHT FIXED TROLLEY (11400A70)……	90x78x73cm (W,D,H,) approx.
-HIGHT ADJUSTABLE TROLLEY (11410A70)	90x78x73cm (W,D,H,) approx.
WEIGHT :	
- INCUBATOR……..	32 kg approx.
- HEIGHT FIXED TROLLEY (11400A70)…….	50 kg approx.
- HIGHT ADJUSTABLE TROLLEY (11410A70)	55 kg approx.

13. OGB POLY CARE 2 COMPLIES WITH THE FOLLOWING REGULATIONS:

IEC	601.1 (CEI 62.5)
IEC	601.2.19
EN	55011
EN	61000-4-2
EN	61000-4-3
EN	61000-4-4
EN	61000-4-5
EN	61000-4-1
MEDICAL DEVICE 93/42/CEE CLASS IIb	

14. ECO-COMPATIBLE RECALL and DISPOSAL

This apparatus is an electro-medical device and therefore does not come under the scope of the RoHs Directive.
Conforming to the Directive 2002/96/CE, known as the RAEE Directive, and to the implemented Italian legislation , our electronic and electrical apparatus are marked with the symbol shown below,
provided for by the CEI EN 50419 Standard.
This apparatus must not be disposed of with domestic rubbish/garbage.
For RECALL of rejected equipment, please contact our Customer Assistance Dept (see the first pages of this manual). The apparatus, at the end of its useful life, must be disposed of according to
the Standards in force at that time.

UNI EN ISO 9001:2000 – CERTIFIED QUALITY SYSTEM BY IQNET – No. CERT –IT-37100
UNI CEI ISO 13485 – PARTICULAR REQUIREMENTS FOR MEDICAL DEVICES

CE 0051